CLAIMS

We claim:

1. (Original) An osmotic device comprising:

a core comprising a therapeutically effective amount of pseudoephedrine, at least one pharmaceutical excipient and at least one osmotic agent, wherein the core provides a controlled release of pseudoephedrine;

a semipermeable membrane surrounding the core and having at least one passageway there through; and

a drug-containing water soluble or erodible coat comprising a therapeutically effective amount of fexofenadine, wherein the external coat provides a rapid release of fexofenadine; and

wherein:

at least 93±7% of the pseudoephedrine (PS) is released within 23 hours, and at least 65% of the H1 antagonist is released within about 40 minutes after exposure of the osmotic device to an aqueous environment.

2. (Original) The osmotic device of claim 1, wherein: 1) 20±7.1% of the PS is released within 3 hours; 2) 51.5±16.3% of the PS is released within 7 hours; 3) 75±14.1% of the PS is released within 11 hours; and 4) 86.5±9.2% of the PS is released within 15 hours after exposure of the osmotic device to an aqueous environment.

3. (Original) The osmotic device of claim 1, wherein: 1) 15-25% of the PS is released within about 3 hours; 2) 46-57% of the PS is released within about 7 hours; 3) 70-80% of the PS is released within about 11 hours; and 4) 85-89% of the PS is released within about 15 hours; and 5) at least 93% of the PS is released within about 23 hours after exposure of the osmotic device to an aqueous environment.

4. (Original) The osmotic device of claim 1, wherein: 1) 15-25% of the PS is released within about 3 hours; 2) 40-63% of the PS is released within about 7 hours; 3) 65-85% of the PS is released within about 11 hours; and 4) 80-93% of the PS is released within about 15 hours; and 5) at least 90% of the PS is released within about 23 hours after exposure of the osmotic device to an aqueous environment.

5. (Original) The osmotic device of any one of claim 1-3 or 4 further comprising an inert water soluble and/or erodible coating disposed between the semipermeable membrane and the drug-containing water soluble coating

6. (Original) The osmotic device of claim 5, wherein at least 75% of the H1 antagonist is released within 40 minutes after exposure of the osmotic device to an aqueous environment.

7. (Original) The osmotic device of claim 6, wherein the drug-containing water soluble and/or erodible coat is sprayed onto the inert water soluble coating.

8. (Original) The osmotic device of claim 5, wherein the osmotic device begins to release pseudoephedrine within about 3 hours after exposure to an aqueous environment.

9. (Original) The osmotic device of claim 5, wherein all of the H1 antagonist is released within 90 min after exposure to an aqueous environment.

10. (Original) The osmotic device of claim 5, wherein all of the H1 antagonist is released within 45 min after exposure to an aqueous environment.

11. (Original) The osmotic device of claim 5, wherein all of the H1 antagonist is released within 20 min after exposure to an aqueous environment.

12. (Original) The osmotic device of claim 5, wherein all of the PS is released within 24 hours min after exposure to an aqueous environment.

13. (Original) The osmotic device of claim 5, wherein the PS is released at a first order, pseudo-first order, zero order or pseudo-zero order rate for a period of at least 12 hours.

14. (Original) The osmotic device of claim 2, wherein the PS is released according to a sigmoidal release profile.

15. (Original) The osmotic device of claim 5, wherein the drug-containing water soluble and/or erodible coat is present in an amount of at least about 25% wt. based upon the total weight of the osmotic device.

16. (Original) The osmotic device of claim 5, wherein the drug-containing water soluble and/or erodible coat is present in an amount of about 25-40% wt. based upon the total weight of the osmotic device.

17. (Original) The osmotic device of claim 5, wherein the drug-containing water soluble and/or erodible coat is present in an amount of about 30-40% wt. based upon the total weight of the osmotic device.

18. (Original) The osmotic device of claim 5, wherein:

the core further comprises an osmagent, a diluent and a binder;

the semipermeable membrane comprises a cellulose ester and a plasticizer;

the inert water soluble and/or erodible coating comprises a water soluble polymer, an opaquant and a filler; and

the drug-containing water soluble and/or erodible coat further comprises a film forming polymer, a water soluble polymer and a disintegrant.

19. (Original) The osmotic device of claim 18, wherein:

the osmagent is selected from the group consisting of sodium chloride, salt, mannitol, acid, sugar, base, calcium salt, sodium salt, and lactose;

the diluent is selected from the group consisting of microcrystalline cellulose, lactose, sucrose, mannitol, cellulose, starch, sorbitol, dibasic calcium phosphate, and calcium carbonate;

the binder is selected from the group consisting of poly(vinylpyrrolidone), povidone, sodium carboxymethylcellulose, alginic acid, poly(ethylene glycol), guar gum, polysaccharide, bentonite clay, sugar, poloxamer, collagen, albumin, gelatin, poly(propylene glycol), and poly(ethylene oxide);

the cellulose ester is selected from the group consisting of cellulose acetate, cellulose acylate, cellulose fatty acid ester, and cellulose acetate phthalate;

the plasticizer is independently selected at each occurrence from the group consisting of poly(ethylene glycol), low molecular weight polymer, citrate ester, triacetin, propylene glycol, glycerin, sorbitol lactate, ethyl lactate, butyl lactate, ethyl glycolate, and dibutylsebacate;

the water soluble polymer is independently selected at each occurrence from the group consisting of hydroxypropyl methylcellulose, poly(vinlypyrrolidone)-(vinyl acetate) copolymer, poly(vinylpyrrolidone), methyl methacrylate, calcium pectinate, poly(ethylene-vinyl acetate), hydroxylalkyl alkylcellulose, polyvinylalcohol, polyethylene oxide, a blend of gelatin and polyvinyl-pyrrolidone, gelatin, glucose, saccharide, povidone, copovidone, and polysaccharide gum;

the film forming polymer is selected from the group consisting of hydroxypropyl methylcellulose, and poly(vinylpyrrolidone);

the disintegrant is selected from the group consisting of crospovidone, bentonite clay, microcrystalline cellulose, starch, carboxymethylcellulose, alginate, sodium starch glycolate, and gum.

20. (Original) The osmotic device of claim 19, wherein:

the opaquant is selected from the group consisting of titanium dioxide and talc; and

the filler is selected from the group consisting of talc and starch.

21. (Original) The osmotic device of claim 18, wherein:

the pseudoephedrine is present in an amount ranging from about 228-252 mg;

the osmagent is present in an amount ranging from 73-90 mg;

the diluents are present in an amount ranging from 96-144 mg;

the binders are present in an amount ranging from 8-12 mg;

the cellulose esters are present in an amount ranging from 38-57 mg;

fexofenadine is present in an amount ranging from 171-189 mg;

the film-forming polymer in the drug-containing water soluble and/or erodible coating is present in an amount ranging from 4-6 mg; and

the disintegrant in the drug-containing water soluble and/or erodible coat is present in an amount ranging from 12-18 mg.

22. (Original) The osmotic device of claim 5, wherein about 90% of the fexofenadine has a particle size of less than about 20 μ and the osmotic device has a content uniformity for fexofenadine of less than about 3.5%.

23. (Original) A method of treating a respiratory congestion related disorder in a mammal, comprising the step of administering an osmotic device according to claim 5.

24. (Original) A method of treating a respiratory congestion related disorder in a mammal, comprising the step of administering an osmotic device according to claim 6.

25. (Original) A method of treating a respiratory congestion related disorder in a mammal, comprising the step of administering an osmotic device according to claim 8.

26. (Original) A method of treating a respiratory congestion related disorder in a mammal, comprising the step of administering an osmotic device according to claim 13.

27. (Original) A method of treating a respiratory congestion related disorder in a mammal, comprising the step of administering an osmotic device according to claim 14.

28. (Original) A method of treating a respiratory congestion related disorder in a mammal, comprising the step of administering an osmotic device according to claim 16.

29. (Original) A method of treating a respiratory congestion related disorder in a mammal, comprising the step of administering an osmotic device according to any one of claims 1-3 or 4.

30. (Original) The osmotic device of any one of claims 1-3 or 4, wherein pseudoephedrine is released according to a first order, pseudo-first order, zero order, pseudo-zero order or sigmoidal release profile for a period of at least 12 hours.

31. (Original) The osmotic device of claim 30, wherein about 90% of the fexofenadine has a particle size of less than about 20 μ and the osmotic device has a content uniformity for fexofenadine of less than about 3.5%.

32. (Original) The osmotic device of claim 30, wherein the drug-containing water soluble and/or erodible coat is present in an amount of at least about 25% wt. based upon the total weight of the osmotic device.

33. (Original) A method of treating a respiratory congestion related disorder in a mammal, comprising the step of administering an osmotic device according to claim 30.

34. (Original) A method of treating a respiratory congestion related disorder in a mammal, comprising the step of administering an osmotic device according to claim 31.

35. (Original) A method of treating a respiratory congestion related disorder in a mammal, comprising the step of administering an osmotic device according to claim 32.

36. (New) The osmotic device of claim 1, wherein the semipermeable membrane covers and coats the core.

37. (New) The osmotic device of claim 36, wherein the semipermeable membrane has been formed by spraying a film-forming solution directly onto the core.

38. (New) The osmotic device of claim 37 further comprising an inert water soluble and/or erodible coating disposed between the semipermeable membrane and the drug-containing water soluble coating.

39. (New) The osmotic device of claim 38, wherein the drug-containing water soluble and/or erodible coat is sprayed onto the inert water soluble coating.

40. (New) The osmotic device of claim 38, wherein the PS is released at a first order, pseudo-first order, zero order or pseudo-zero order rate for a period of at least 12 hours.

41. (New) The osmotic device of claim 38, wherein the PS is released according to a sigmoidal release profile.

42. (New) The osmotic device of claim 38, wherein the drug-containing water soluble and/or erodible coat is present in an amount of at least about 25% wt. based upon the total weight of the osmotic device.

43. (New) The osmotic device of claim 38, wherein about 90% of the fexofenadine has a particle size of less than about 20 μ and the osmotic device has a content uniformity for fexofenadine of less than about 3.5%.

44. (New) A method of treating a respiratory congestion related disorder in a mammal, comprising the step of administering an osmotic device according to any one of claim 36-42 or 43.